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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,911	08/10/2000	Badri N. Prasad	6759	6357

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EXAMINER
KOPPIKAR, VIVEK D

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
01/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	09/635,911	PRASAD ET AL.
	Examiner	**Art Unit**	
	VIVEK D. KOPPIKAR	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on _30 October 2007_.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1,4,6,29,32-34,37,39,43,49,52,53,57,58,63 and 66-68_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _1, 4, 6, 29, 32-34, 37, 39, 43, 49, 52, 53, 57, 58, 63 and 66-68_ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All   b) ☐ Some * c) ☐ None of:

        1. ☐ Certified copies of the priority documents have been received.

        2. ☐ Certified copies of the priority documents have been received in Application No. _____.

        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1.   Claims 1-19, 21-61 and 63-68 have been examined in this application. This

communication is the first action on the merits since the applicants filed an Request for

Continued Examination (RCE) on October 30, 2007.

Claim Rejections - 35 USC § 103

2.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth
> in section 102 of this title, if the differences between the subject matter sought to be patented and the prior
> art are such that the subject matter as a whole would have been obvious at the time the invention was made
> to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be
> negatived by the manner in which the invention was made.

3.   Claims 1, 4, 16-17, 21-24, 27-29, 31-32, 37, 39, 43, 49, 52, 53, 63, and 66-67 are rejected

under 35 U.S.C. 103(a) as being unpatentable over Lash (US 2001/0020229 A1) in view of US

Patent Application Publication 2004/0199332 to Iliff in view of US Patent Application

Publication 2002/0004725 to Martin.

(A) As per claim 1, Lash discloses an automated method for predicting the likelihood

that a patient will acquire high medical service utilization characteristics, thereby becoming a

high-cost patient to a managed care organization relative to other patients, within a given period

of time based on a previous time period (Abstract, par. 22) comprising:

compiling a plurality, wherein the provider claims for the plurality of members occur

within a base period and include a plurality of health conditions (Lash: Section [0023]);

calculating a burden of illness score for the each member (Lash: Section [0038]);

computing a utilization score for each health plan t-he member based on the burden of

illness score and at least one explanatory variable, wherein the explanatory variable is derived

from demographic data or prior healthcare utilization data associated with the member (Lash:

Section [0038]);

using the utilization score to predict healthcare resource consumption in the target period

by at least one plan member (Lash: Section [0006]).

As per the recitation of "each of a plurality of members in a health plan," the Examiner

respectfully submits that Lash teaches computing scores based on a period of time which is a

form of Applicant's recitation of "each of a plurality of members in a health plan" because

Applicant's invention also uses a base period of time.

Assuming *arguendo* that Lash fails to teach computer utilization scores for each of a

plurality of members of a health plan, the Examiner respectfully submits that this limitation is

obvious as evidenced by the teachings of Lash. As per the recitation of utilization scores being

computed for "each of a plurality of members in a health plan" rather than on a filtered set of

data, the courts have held that the omission of a step and its function is obvious if the function of

the step is not desired. *See Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). *See also*

In re Larson, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188

USPQ 7 (CCPA 1975). In this case, the elimination of the step of filtering data to only analyze a

subset of data as disclosed in Lash, thus allowing analysis of "each member of a health plan," is

obvious to allow a managed care organization to accurately predict which patients will have high

utilization of medical services (Lash; par. 6). As such, these changes do not present a patentable

distinction over the applied prior art of record.

Lash does not teach the following feature which is taught by Iliff (Section [0010]):

storing a plurality of disease categories representing a plurality of health conditions or diseases; storing category weight data, wherein each category weight data comprises a value associated with each stored diseases category, wherein each weight value associated with a stored disease category represents an average incremental cost for a plan member associated with the presence of the associated stored disease category during the base period; for each of the plurality of health plan members, identifying each stored disease category present in the plurality of provider claims for the member.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Martin in view of Lash with the teachings from Iliff with the motivation of having a means of diagnosing a patient's medical complaint, as recited in Iliff (Section [0004]).

Lash in view of Iliff do not teach the following features which are taught by Martin:

wherein the burden of illness score is a number calculated by summing the stored weight values associated with each disease category identified in the member's provider claims (Note: The Office takes the position that this step is essentially a step wherein a total risk (of illness) is calculated by considering many different factors that contribute to the risk (of illness) and then multiplying each factor by a weighing factor to arrive at a intermediary value and then summing these intermediary values to arrive at a total risk (of illness) value).

However, Martin teaches this feature (Figure 3 (Items 310, 314, 318 and 322 and Section [0114]). At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the teachings of Lash with this aforementioned teaching from Martin with the motivation of having a means of arriving at a total risk value that takes both quantifies and

take into account all sub-factors (segments) which contribute to a risk factor, as recited and

illustrated in Martin (Figure 3 and Section [0114]).

(B) As per claims 4, Lash discloses using pharmacy claims, medical claims, or both and in one

embodiment of Lash the claims can include only medical claims and the disease categories are

CCG categories. (par. 24-25, 59).

(D) As per claim 16, Lash discloses that many different claims variables and encounter data

(e.g., an ER visit) are available for potential use in the model. the number of hospital in-patient

days for respiratory-related admissions involving ICU care at any time during the admission

(ICUDAY); the number of hospital in-patient days for respiratory related admissions not

involving ICU care at any time during the admission (SPDAY); the number of hospital in-

patient days for non-respiratory related admissions (OTHRDAY); whether the patient has had

one respiratory related ER visit in the index year (ERRESPC1); whether the patient has two or

more respiratory related ER visits in the index year (ERRESPC2); the number of the patient's

non-respiratory related ER visits (ER_OTHR); the number of respiratory related office visits of

the patient (OV_RESP); the number of non-respiratory related office visits (OV_OTHR); the

number of prescription drug claims (RXCNT); the presence or absence of an allergy-related

diagnosis (CMALERG2); the presence or absence of a respiratory infection diagnosis

(CMINFEC2); the presence or absence of another respiratory related (comorbid) diagnosis

(CNIRSPIR2); the presence or absence of hypertrophied nasal turbinate diagnosis

(CMNAST2); and the presence or absence of respiratory complication diagnosis (CONDLIC).

Of course, other claims data and encounter information can also be stored and used in the

patient database. Lash also teaches that prior to the calculating step, determining the presence of

a plurality of medical episodes in the plurality of provider claims and grouping the plurality of

provider claims gala into-one or more groups based on a medical episode (par. 49).

(E) As per claim 17, Lash fails to expressly disclose Clinical Care Groups. However, Lash

discloses placing the plurality of provider claims data into groups based on a medical episode

(see par. 49). It is respectfully submitted that using a specific grouping (i.e. Clinical Care

Groups) is another form of grouping. The skilled artisan would have it obvious to include

another grouping schema within the method of Lash. The motivation being to provide a flexible

grouping system when generating models thus increasing the usefulness of the models.

(F) As per claim 63, Lash discloses assigning the pharmacy claims to one of a plurality of

groups based on a relationship to corresponding medical claim indicating the presence of the

medical episode (see the number of prescription drug claims, the presence or absence of another

respiratory related (comorbid disease), the presence or absence of hypertrophied nasal turbinate

diagnosis (CMNAST2), and the presence or absence of respiratory complication diagnosis

(CONDLIC)) (par. 49-54).

(I) As per claims 21-24 and claim 66-67, Lash discloses the weighing coefficients relating to:

comorbidity (par. 49), complications (see Complic2 in Table 1), age, and sex (par. 49-54).

(J) As per claims 27-29 and 31-32, Lash discloses the variables pertaining to age, sex, number

of chronic claims, such as respiratory claims and non-respiratory claims, the number of ER

visits and office visits, the number of prescription drug claims pertaining to a respiratory

disease, and the cost of medical services used by a patient in a time period (par. 10, 37, 49-54).

(K) As per claim 38, Lash discloses using medical claims and pharmacy claims (par. 59).

Although Lash does not expressly disclose calculating a second score based on information in

both the pharmacy claims and the medical claims, it is respectfully submitted that using both sets of claims would have been an obvious modification to Lash with the motivation of ensuring the accuracy of the model. (See Lash's discussion of calibrating the model to predict the true, high service use population by using "goodness-of-fit testing" to determine whether the model is good. Data from a second database is inserted into the model to determine whether it is a good fit (par. 61)).

(L) As per claims 37, Lash discloses using pharmacy claims and isolating patients having a score above a certain threshold, for example 90% (par. 40-42, 44, 59).

(M) As per claim 39, Lash discloses calibrating the model by comparing the score against the resource utilization for a known target year (par. 60-64).

(O) As per claim 43, Lash discloses calibrating the model by comparing a score against utilization for a known target period, where the utilization is for asthma related use of services (par. 60-64).

(R) As per claims 49, Lash discloses an automated method for predicting the likelihood that a patient will acquire high medical service utilization characteristics, thereby becoming a high-cost patient to a managed care organization relative to other patients, within a given period of time based on a previous time period (Abstract, par. 22) comprising:

      compiling pharmacy claims for each of a plurality members of a health plan, wherein the pharmacy claims for the plurality of members occur within a base period and include a plurality of health conditions and drug categories(Lash: Section [0023]);

      calculating a burden of illness score for the each member based on the member's plurality of provider claims (Lash: Section [0038]);

wherein the utilization score is a weighted sum of the at least one explanatory variable

and the burden of illness score (Lash: Sections [0038] and [0050]);

computing a utilization score for each health plan t-he member based on the burden of

illness score and at least one explanatory variable, wherein the explanatory variable is derived

from demographic data or prior healthcare utilization data associated with the member (Lash:

Section [0038]);

using the utilization score to predict healthcare resource consumption in the target period

by at least one plan member (Lash: Section [0006]).

As per the recitation of "each of a plurality of plan members," the Examiner respectfully

submits that Lash teaches computing scores based on a period of time which is a form of

Applicant's recitation of "each of a plurality of plan members" because Applicant's invention

also uses a base period of time.

Assuming *arguendo* that Lash fails to teach computer utilization scores for each of a

plurality of members of a health plan, the Examiner respectfully submits that this limitation is

obvious as evidenced by the teachings of Lash. As per the recitation of utilization scores being

computed for "each of a plurality of plan members" rather than on a filtered set of data, the

courts have held that the omission of a step and its function is obvious if the function of the step

is not desired. *See Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). *See also In re*

Larson, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ

7 (CCPA 1975). In this case, the elimination of the step of filtering data to only analyze a subset

of data as disclosed in Lash, thus allowing analysis of "each of a plurality of plan members," is

obvious to allow a managed care organization to accurately predict which patients will have high

utilization of medical services (Lash; par. 6). As such, these changes do not present a patentable

distinction over the applied prior art of record.

Lash does not teach the following feature which is taught by Iliff (Section [0010]):

storing a plurality of disease categories representing a plurality of health conditions or

diseases; storing category weight data, wherein each category weight data comprises a value

associated with each stored diseases category, wherein each weight value associated with a

stored disease category represents an average incremental cost for a plan member associated with

the presence of the associated stored disease category during the base period; for each of the

plurality of health plan members, identifying each stored disease category present in the plurality

of provider claims for the member.

At the time of the invention, it would have been obvious for one of ordinary skill in the

art to have modified Martin in view of Lash with the teachings from Iliff with the motivation of

having a means of diagnosing a patient's medical complaint, as recited in Iliff (Section [0004]).

Section [0010]):

Lash in view of Iliff do not teach the following features which are taught by Martin:

wherein the burden of illness score is a number calculated by summing the stored weight

values associated with each disease category identified in the member's provider claims (Note:

The Office takes the position that this step is essentially a step wherein a total risk (of illness) is

calculated by considering many different factors that contribute to the risk (of illness) and then

multiplying each factor by a weighing factor to arrive at a intermediary value and then summing

these intermediary values to arrive at a total risk (of illness) value).

However, Martin teaches this feature (Figure 3 (Items 310, 314, 318 and 322 and Section [0114]). At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the teachings of Lash with this aforementioned teaching from Martin with the motivation of having a means of arriving at a total risk value that takes both quantifies and take into account all sub-factors (segments) which contribute to a risk factor, as recited and illustrated in Martin (Figure 3 and Section [0114]).

(U) As per claim 52, Lash discloses the target period being later than the base period (par. 57-59, claim 1, claim 3).

(V) As per claim 53, Lash discloses a targeted time frame (par. 22, 24, 63, claim 3). It is respectfully submitted that this could be the same time period as the base time period.

4.   Claims 6-15, 25-26, 57-61, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (US 2001/0020229 A1) as applied to claim 1 and 50, and further in view of Wong et al. (5,976,082).

(A) As per claim 6, Lash does not explicitly disclose cleaning the data to remove erroneous information by comparing categories of the data set to acceptable values. Wong discloses cleaning data and performing quality checks by using threshold values to check whether an imbalance exists in the data, whether claims need to be rejected, or if multiple claims exist (col. 3 line 40 to col. 4 line 44, col. 6 lines 32-45, col. 8 lines 23-35). At the time the invention was made, it would have been obvious to include the features of Wong within the method taught by Lash with the motivation of increasing the accuracy of predictions made by a MCO to identify patients who will become or remain high-use patients, thus reducing costs for healthcare (Lash; par. 6).

(G) As per claims 58, Wong discloses using ICD-9 codes and therapeutic classes to assign diseases into appropriate subclasses (col. 6 lines 17-32, col. 9 lines 43-63). Wong discloses assigning prescribed medications including the drug codes into drug therapeutic classes, specifically DM therapeutic class codes (Figures 2-5, col. 7 lines 37-47, col. 11 lines 14-68, Appendix III). Although Wong fails to expressly recite CCG or CCG classes or categories, it is respectfully submitted that the skilled artisan could use another form of classes other than ICD-9 class codes as disclosed by Wong. The motivation being to provide a flexible coding system when generating models thus increasing the usefulness of the models.

(H) As per claim 68, Wong discloses the parameter estimates including the total costs, in-patient hospital costs, emergency room costs, doctor costs, cardiovascular costs, and CHF costs, wherein the costs are associated with an ICD-9 code (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(J) As per claim 57, Lash does not explicitly disclose cleaning the data to remove erroneous information by comparing categories of the data set to acceptable values. Wong discloses cleaning data and performing quality checks by using threshold values to check whether an imbalance exists in the data, whether claims need to be rejected, or if multiple claims exist (col. 3 line 40 to col. 4 line 44, col. 6 lines 32-45, col. 8 lines 23-35). At the time the invention was made, it would have been obvious to include the features of Wong within the method taught by Lash with the motivation of increasing the accuracy of predictions made by a MCO to identify patients who will become or remain high-use patients, thus reducing costs for healthcare (Lash; par. 6).

5.   Claims 33-34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (US

2001/0020229) as applied to claim 1, and further in view of Lockwood (5,706,441).

(A) As per claims 33-34, the teachings of Lash in the rejections above are incorporated herein.

       Lash discloses calculating a probability that a patient with be a high use patient of

medical resources in the following year, wherein the score/probability is scaled to run from 0 to

100, with the higher number meaning a greater probability that the patient will become high-cost

(par. 41, 49-56). Lash does not expressly disclose the step of diving the score by an average

score for the group or by an average score for a benchmark group.

       Lockwood discloses comparing the severity scores for sickness episodes against

benchmarks by dividing the scores with the benchmarks and comparing a score by the average

score for a group (col. 11 line 44 to col. 13 line 41).At the time the invention was made, it would

have been obvious to one of ordinary skill in the art to combine the teachings of Lockwood

within the method of Lash with the motivation of identifying and assessing high risk patients

(par. 41, 49-56).

Response to Arguments

6.   (a)   Applicant's arguments with respect to the pending claims regarding the Lash

reference have been considered but are moot in view of the new grounds of rejection over the

Iliff reference.

       (b)   Applicants arguments regarding the Martin reference have been fully considered

but they are not persuasive. The office takes the position that Martin does in fact teach a means

by which a plurality of disease categories are identified, weight values representing incremental

cost associated with the presence of disease conditions and associated with each identified

category are summed to generate a burden of illness score, and a utilization score is calculated as

a function of the burden of illness score and one or more explanatory variables (Martin: Section

[0114]). The "totalnew" function that exists in Martin that applicants claim is non-analogous to

the method of calculating the burden of illness score in their invention only exists in one

embodiment of Martin (Martin: Section [0065]), however, as noted above, Martin does in fact

teach the claimed method (Martin: Section [0114]). Moreover, motivation exists for combining

Martin with Lash as both the combined teachings of Lash in view of Iliff relate to a non-

homogenous patient group data (Iliff: Section [010]) while Martin also relates to non-

homogenous patient group data (Martin: Section [0114]), wherein non-homogenous means

analyzing patients who have various diseases.

Conclusion

7.   Any inquire concerning this communication or earlier communications from the

examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109.

The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's

supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for

this group are either (571) 273-8300 or (703) 872-9326 (for official communications including

After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information

Retrieval (PAIR). Information regarding the status of an application can be obtained from the

(PAIR) system. Status information for published applications may be obtained from either

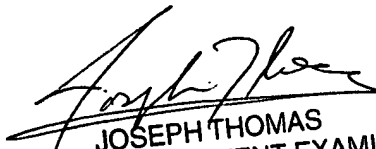Private PAIR or Public PAX. Status information for unpublished applications is available

through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

1/22/2008

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER